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**Treatment of proximal deep vein thrombosis with a novel synthetic compound (SR90107A/ORG31540) with pure anti-factor Xa activity: A phase II evaluation. The Rembrandt Investigators.**

[No authors listed]

**BACKGROUND:** Patients with venous thromboembolism require initial treatment with an immediate-acting anticoagulant, low-molecular-weight heparin. We evaluated a novel synthetic factor Xa inhibitor (SR90107a/ORG31540) as an alternative treatment. **METHODS AND RESULTS:** A randomized-parallel-group, phase II trial to assess the efficacy and safety of SR90107a/ORG31540 (5, 7.5, or 10 mg once daily) relative to low-molecular-weight heparin (dalteparin, 100 IU/kg twice daily) in symptomatic proximal deep vein thrombosis. The primary outcome measure was the change in thrombus mass, assessed by ultrasonography of the leg veins and perfusion lung scintigraphy, performed at baseline and day 7+/-1. A positive outcome was defined as improvement of the ultrasound and/or perfusion scan result without deterioration of either test. Other outcome measures included symptomatic, recurrent venous thromboembolism and major bleeding for a period of 3 months. All outcomes were interpreted with the observer unaware of treatment allocation. A positive primary outcome was observed in 46 of 100 (46%), 52 of 108 (48%), 48 of 115 (42%), and 56 of 115 (49%), respectively, of the subjects given 5, 7.5, or 10 mg SR90107a/ORG31540 or dalteparin. There were 8 recurrent thromboembolic complications (2.4%) in the 334 patients treated with SR90107a/ORG31540 and 6 (5.0%) in the 119 dalteparin patients, a difference of 2.6% in favor of SR90107a/ORG31540 (95% CI -2.1% to 10. 1%). The incidence of bleeding was low and was similar among the groups. **CONCLUSIONS:** The factor Xa inhibitor SR90107a/ORG31540 appears to be an effective and safe treatment for patients with deep vein thrombosis across a wide range of doses. This synthetic compound merits evaluation in phase III studies.

**Publication Types:**

- Clinical Trial
- Clinical Trial, Phase II
- Randomized Controlled Trial

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